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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,562	06/17/2005	Kristopher Buchanan	09138.0070	2677

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1775

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,562	Applicant(s) BUCHANAN ET AL.	
	Examiner NATHAN A. BOWERS	Art Unit 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75,90-113,116-118,120 and 121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75,90-113,116-118,120 and 121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>121410</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 December 2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 75 and 90-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reichler (US 5578270) in view of Tseung (US 20030099573).

With respect to claim 75, Reichler discloses an automated system for processing a biological sample using a plurality of work stations. At least one removable reagent station (Figure 3:154) is positioned within the automated system, as are a plurality of carrier retention devices (Figure 3:78, 80, 82, 84). Each carrier retention device is in direct communication with a separate active temperature regulation element for heating platens 92, 94 and 100. See column 11, lines 17-53. Reichler teaches in column 5, line 52 to column 6, line 20, column 8, lines 43-50, column 16, lines 26-63, column 18, lines 57-63 and column 20, lines 39-50 that samples are moved between various work stations using a robotic member (Figure 3:190) in communication with a pipette and pressurization means. Reichler, however, does not expressly state that the reagent and carrier work stations are provided within drawers capable of facilitating the insertion and removal of objects during the processing protocol without interrupting the movement of the robotic member.

Tseung discloses an automated system for processing a biological sample. Tseung teaches that a robotic member (Figure 1:22) is used to automatically add and withdraw reagents and sample solution from a plurality of specimen slides (Figure 1:12). Tseung teaches in paragraphs [0035]-[0037] that slides and reagent containers (Figure 1:50) are provided within drawers that allow for the removal of slides and reagent containers without interrupting the movement of the robotic member.

Reichler and Tseung are analogous art because they are from the same field of endeavor regarding biochemical sample processing stations.

At the time of the invention, it would have been obvious to provide each of the Reichler carrier retention devices and reagent stations within a separate slideably removable drawer. As evidenced by Tseung, this would allow for the removal of a specified carrier retention device without interfering with the operation of the robotic member, as well as the continued processing of other carrier retention devices. More specifically, lateral displacement of each Reichler carrier retention device 78, 80, 82, 84 prior to slide removal would prevent pivotable arm 102 from interfering with the movement of the robotic member.

With respect to claims 90-95, Reichler and Tseung disclose the system in claim 75 wherein the processing system is capable of executing a variety of different techniques. The apparatus of Reichler is fully capable of operating as either an automated immunohistochemistry processing system or a fluorescent in-situ

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hybridization processing system. The apparatus is further designed to accommodate DNA probe and/or antibody based staining procedures.

With respect to claims 96-98, Reichler and Tseung disclose the system in claim 95 wherein an active temperature reduction element is additionally provided. The use of temperature reduction elements, such as Peltier coolers, is considered to be well known in the art.

With respect to claims 99-101, Reichler and Tseung disclose the system in claim 95 wherein the active temperature regulation element comprises a temperature ramp up and ramp down element, thus inducing regulated temperature increases and decreases within the sample.

2) Claims 102-113, 116-118, 120 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reichler (US 5578270) in view of Tseung (US 20030099573) and Ammann (US 20050233370).

With respect to claims 102-108, Reichler and Tseung disclose the system set forth in the rejections above. Reichler discloses at least one container having a reagent therein, as well as a sample carrier retention device. Sample temperature control elements are provided for regulating the temperature of the contents of the sample carrier retention device. Reichler, however, does not expressly disclose that reagent

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temperature control elements are provided for regulating the temperature of reagents before they are applied to the sample.

Ammann discloses an automated system for processing a plurality of reaction receptacles each capable of holding and transporting a sample. Reaction receptacles are transported to an arrangement of incubators (Figure 4:600,602,604,606) where they are maintained at a predetermined temperature. Paragraphs [0130], [0332] and [0337]-[0369] state that reagents are stored in separate containers located within a reagent cooling bay (Figures 35-39). Ammann teaches that thermoelectric modules and fan units provide the desired cooling capacity, and are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers.

Reichler and Ammann are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to equip Reichler's reagent storage containers with cooling elements and a control system capable of regulating the temperature within the reagent storage containers. Reagents typical of microarray processing systems are known in the art to be temperature sensitive and susceptible to degradation if maintained under undesirable conditions. As evidenced by Ammann, it is well known in the art to keep reagents at cool temperatures during storage to ensure that they do not prematurely expire.

With respect to claims 109-113, Reichler, Tseung and Ammann disclose the apparatus set forth in claim 102 as set forth in the 35 U.S.C. 103 rejections above. In

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addition, Reichler indicates that a sample temperature control element is provided to ramp up and ramp down the temperature of the sample maintained within the carousel retention device during processing. This has been described in the rejections above.

With respect to claims 116 and 117, Reichler, Tseung and Ammann disclose the apparatus set forth in claim 102 as set forth in the 35 U.S.C. 103 rejections above. The reagent containers of Reichler are further considered to be fully capable of retaining a rinse buffer. Ammann also discloses rinsing and washing steps throughout the reference. As described above, Ammann further teaches that thermoelectric modules and fan units are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers.

With respect to claims 118, 120 and 121, Reichler, Tseung and Ammann disclose the apparatus set forth in the 35 U.S.C. 103 rejections above. As previously noted with regard to Reichler, Tseung and Ammann, it is understood that since each slide is independently and removably mounted over a different thermal management module, each slide may be inserted or removed during the processing protocol without interrupting a processing of another sample.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 75, 90-113, 116-118, 120 and 121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

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claims 1-12, 14-19, 21-23, 25, 27-30 and 32-36 of copending Application No. 10/538964. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of copending Application No. 10/538964 include limitations drawn to a biological sample processing apparatus comprising at least one reagent container and slide section provided on drawers capable of facilitating the addition and removal of reagents without interrupting the operation of robotic element.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 75, 90-113, 116-118, 120 and 121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-71 of copending Application No. 10/539308. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of copending Application No. 10/539308 include limitations drawn to a biological sample processing apparatus comprising at least one reagent container and slide section provided on drawers capable of facilitating the addition and removal of reagents without interrupting the operation of robotic element.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 75, 90-113, 116-118, 120 and 121 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33

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of U.S. Patent No. 7,875,245. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of U.S. Patent No. 7,875,245 include limitations drawn to a biological sample processing apparatus comprising at least one reagent container and slide section provided on drawers capable of facilitating the addition and removal of reagents without interrupting the operation of robotic element.

Response to Arguments

Applicant's arguments filed 14 December 2010 with respect to the 35 U.S.C. 103 rejections involving Custance in view of Reichler and Custance in view of Reichler and Kalra have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Reichler and Tseung.

Tseung more clearly discloses a system in which reagents and sample carrier devices are provided on slidingly withdrawable drawers capable of allowing for the insertion and removal of objects without interfering with the movement of a robotic member. Although Tseung discloses the use of a single drawer for containing every sample carrier, it is well within the purview of one of ordinary skill to provide each of the Reichler sample carriers 78, 80, 82, 84 with a separate and independently addressable drawer.

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Conclusion

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathan A Bowers/
Primary Examiner, Art Unit 1775